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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,664	05/19/2004	Aladar Szalay	17248-004002 (4804B)	7765

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Stephanie Seidman
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130-2081

EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/849,664

Applicant(s)

SZALAY ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-32 are presently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 3-12, 14-15, 20-27, and 30, drawn to compositions for treatment or diagnosis/visualization of wounded/inflamed tissue or disease associated therewith, wherein the composition comprising a bacterial cell containing a DNA sequence encoding a detectable protein or a protein capable of inducing a detectable signal, classified in class 435, subclass 252.1.
- II. Claims 3-10, 16-27, and 30, drawn to compositions for treatment or diagnosis/visualization of wounded/inflamed tissue or disease associated therewith, wherein the composition comprising a mammalian cell containing a DNA sequence encoding a detectable protein or a protein capable of inducing a detectable signal, classified in class 424, subclass 93.1.
- III. Claims 3-13, 20-27 and 30, drawn to compositions for treatment or diagnosis/visualization of wounded/inflamed tissue or disease associated therewith, wherein the composition comprising a virus containing a DNA sequence encoding a detectable protein or a protein capable of inducing a detectable signal, classified in class 424, subclass 93.2.
- IV. Claim 31, drawn to a method comprising monitoring the efficacy of an antibiotic regimen, classified in class 435, subclass 4.

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- V. Claim 31, drawn to a method comprising evaluating the resistance of a suture to bacterial colonization, classified in class 435, subclass 7.22.
- VI. Claim 31, drawn to a method comprising evaluating the resistance of an implantable material to bacterial colonization, classified in class 128, subclass 899.

***Claim 32 will be rejoined with any properly elected invention.**

Claims 1-2 link(s) inventions I-III. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

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different inventions are not disclosed as capable of use together and require different compositions, which provide different modes of operation, requiring distinct, non-coextensive considerations. To wit, the bacterial cells are independent living organisms, and need to be considered for those types of cells that may exist in the body, overcome the body's defenses, and produce the desired effect. The mammalian cells need to be considered as to those types of cells which may also enter the body, but do not have the same ability to adjust to circumstance that the bacterial cells do, and as such would require distinct considerations for how to administer such cells. The viruses, distinct from the cells, must be considered for those viruses that can invade the cells of the body, transcribe the proteins encoded and exert an effect through further expression of the proteins. Each of these distinct, non-coextensive considerations would pose a serious burden to consider any two of the inventions together.

Groups IV-VI are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and require different steps, requiring distinct, non-coextensive considerations. To wit, Group IV requires a consideration of how to monitor the efficacy of an antibiotic regimen, Group V requires a consideration of how to evaluate the resistance to bacterial colonization in a suture, and Group VI requires a consideration of the implantable materials which may be evaluated for resistance to colonization. Each of these distinct non-coextensive considerations would pose a serious burden on the Examiner to consider any two groups together.

It is noted that certain groups contain classifications in common, to wit, classifications 424 and 435 are common to multiple groups. However, these classifications are so broad that the search within each classification would be different and distinct and non-coextensive between any two groups. To wit, Group 424 encompasses all bio-affecting compositions and Group 435 encompasses all molecular biology and microbiology testing processes.

Because these inventions are distinct for the reasons given above and the search required for any single group is not required of any other, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species, within several sets of genera, of the claimed invention:

- (i) Applicant is required to choose one of the three proteins capable of producing a detectable signal of claims 5-6;
- (ii) Applicant is required to choose one of the four genera of detectable signals of claims 9-10;
- (iii) Applicant is required to choose one of the four bacterium of claims 14-15;
- (iv) Applicant is required to choose either autologous or heterologous stem cells, of claims 18-19;
- (v) Applicant is required to choose either an enzyme causing cell death or an enzyme causing the digestion of debris of claim 20;
- (vi) Applicant is required to choose one of the 10 diseases of claims 21-22 and 25-26; and
- (vii) Applicant is required to choose one of the four vectors of claim 29 (It is noted that if Applicant makes a choice that is inconsonant with the invention elected, e.g., choosing an

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invention requiring administration of a mammalian cell, but then electing a virus in this election, Applicant receive a non-responsive election notice, as such would be inconsonant with the general purpose of such elections: to reduce the burden of examination.).

Applicant should make a single choice for each of (i)-(vii), whether or not such election falls within the elected invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2, 5-6, 11-12, 16-17, and 31-32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1633
2C55 Remsen Building
(571) 272-0729


DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER